Remarks

The Office Action mailed September 22, 2004 has been received and reviewed. Claims 2-5, 7-11, 17, and 25-28 having been amended, claims 1, 6, and 12-16 having been cancelled, without prejudice, and claims 29-39 having been added, the pending claims are claims 2-5, 7-11 and 17-39. Claims 17-28 being withdrawn from examination, as drawn to non-elected inventions, claims 2-5, 7-11, and 29-39 are currently under examination. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for the amended and new claims is found throughout the specification. For example, support for amended claim 9 and new claim 39 can be found on page 6, lines 9-19; support for new claim 29 can be found on page 9, lines 12-31; support for new claim 30 can be found on page 11, line 28-29; support for new claims 31-33 can be found on page 13, lines 29 to page 14, line 7; and support for new claims 34-38 can be found on page 5, lines 6-10.

Restriction Requirement

Applicants continue to traverse the Restriction Requirement mailed July 1, 2004. Applicants respectfully request the rejoinder and examination of claims 27 and 28 (Group III) along with the elected claims of Group I. Withdrawn claims 27 and 28 are drawn to a "fertility impairing vaccine comprising an avian zona pellucida protein or an immunogenic fragment thereof and a porcine zona pellucida protein or an immunogenic fragment thereof." As explained in the specification on page 2, lines 9-29, the preparation and use of porcine zona pellucida protein (pZP) as a vaccine is known, with pZP having "been used for more than eight years in horses with no known adverse effects" (page 2, lines 16-17 of the specification). Applicants respectfully submit that the burden of searching and examining withdrawn claims 27 and 28 along with claims 2-5 and 7-11 is not undue.

Further, pursuant to "Guidance on Treatment of Product and Process Claims in Light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b)" (1184 O.G. 86 (March 1996)), Applicants

request, upon identification of an allowable product claim, the rejoinder and examination of non-elected method claims 17-26.

The 35 U.S.C. §112, First Paragraph, Enablement Rejection

The Examiner rejected claims 2-5 and 7-11 under 35 U.S.C. §112, first paragraph, alleging the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner asserted that "the specification, while being enabling for the use of a fertility impairing vaccine comprising avian pellucida protein in birds, does not reasonably provide enablement for the use of a fertility impairing vaccine comprising avian zona pellucida protein in all animals (page 3 of Office Action mailed September 22, 2004). Applicants respectfully disagree and traverse this rejection.

Claims 2-5 and 7-11 are drawn to a fertility impairing vaccine comprising an avian zona pellucida protein, or an immunogenic fragment thereof. As acknowledged by the Examiner, the specification describes how to make (see, for example, Examples I and II (pages 14-16) of the specification) and how to use the claimed vaccine (see, for example, page 12, line 10 to page 14, line 7 and Examples III and IV (pages 16-17) of the specification). As detailed in M.P.E.P. § 2164.01(b), "[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)." Thus, Applicants respectfully submit that the specification provides adequate guidance to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention of claims 2-5 and 7-11.

Further, Applicants are puzzled by this enablement rejection in view of the Examiner's substantiation of the rejection of claims 10 and 11 as anticipated by Waclawek et al. In substantiating the rejection of claims 11 and 12 as anticipated by Waclawek et al., the Examiner

asserted that the injection of the avian protein chZPC into rabbits initiates the production of antibodies, and "[a]s such, it is reasonable to conclude that the chZPC composition of Waclawek et al. has the functional properties of being an immunosterilant and an immunocontraceptive (in rabbits)" (see page 9 of the Office Action mailed September 22, 2004). The Examiner acknowledges that it is reasonable to conclude that immunization of rabbits with an avian protein will function as an immunosterilant and an immunocontraceptive in a mammal. Thus, Applicants do not understand the Examiner's assertion that the specification, while being enabling for the use of a fertility impairing vaccine comprising avian pellucida protein in birds, does not reasonably provide enablement for the use of such a fertility impairing vaccine in other animals.

Applicants respectfully submit that the specification provides adequate guidance to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention of claims 2-5 and 7-11. Withdrawal of the rejection of claims 2-5 and 7-11 under 35 U.S.C. §112, first paragraph, is respectfully requested.

The 35 U.S.C. §112, First Paragraph, Written Description Rejection

The Examiner rejected claims 2-5 and 7-11 under 35 U.S.C. §112, first paragraph, asserting that the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the Examiner asserted that there is insufficient written description for the recitation "an immunogenic fragment thereof" in claims 2-5 and 7-11 and the recitation "a T cell epitope, a helper T cell epitope, and a B cell epitope" in claim 9 (page 5 of the Office Action mailed September 22, 2004). Applicants respectfully disagree and traverse this rejection.

"To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the

inventor had possession of the claimed invention" (M.P.E.P. § 2163). There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed (Wertheim, 541 F.2d at 262, 191 USPQ at 96) and, generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986)(M.P.E.P. § 2163).

Claims 2-5 and 7-11 are drawn to "an immunogenic fragment thereof" of an avian zona pellucida protein. Applicants submit that the specification provides adequate written description for the claimed "immunogenic fragment thereof." As described in the specification, "[a]n immunogeneic fragment of an avian zona pellucida protein . . . is a peptide fragment . . that elicits an immune response in a subject to which it is administered. An immune response includes either or both a cellular immune response or production of antibodies . . . . For example, an immune response is evidenced by a detectable anti-aZP antibody level in the subject using ELISA" (page 5, line 27 to page 6, line 2 of the specification). Further, Applicants submit that the level of knowledge and skill in the art of immunology and vaccine preparation is very high and that the preparation and inclusion of immunogenic fragments of a protein, such as avian zona pellucida protein, in a vaccine was well known at the time of the instant invention. See, for example, the various vaccines including immunogenic fragments as claimed in U.S. Patent Nos. 5,171,568, 5,840,315, 5,843,460, 5,869,066, 5,897,475, and 5, 976,525. Information which is well known in the art need not be described in detail in the specification. Applicants respectfully submit that the specification provides adequate written description for the claimed "immunogenic fragments thereof." Likewise, Applicants respectfully submit that page 6, lines 9-22 of the specification provides adequate written description for amended claim 9, drawn to "at least one

immune cell epitope from a virus, bacterium or parasite." Withdrawal of this rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 2-5, 10, and 11 under 35 U.S.C. §102(a) as being anticipated by Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239). This rejection is respectfully traversed. Claims 2-5, 10, and 11 are draw to "[a] fertility impairing vaccine comprising an avian zona pellucida protein or an immunogenic fragment thereof and an immunological adjuvant selected from the group consisting of aluminum hydroxide, Acemannan, permulum, synthetic trehalose dicorynomycolate, squalene oil, drakeol, vegetable oil, lecithin, phosphtidyl choline, and combinations thereof." Applicants respectfully submit that Waclawek et al. does not disclose an "immunological adjuvant selected from the group consisting of aluminum hydroxide, Acemannan, permulum, synthetic trehalose dicorynomycolate, squalene oil, drakeol, vegetable oil, lecithin, phosphtidyl choline, and combinations thereof." Thus, the disclosure of Waclawek et al. does not set forth each and every element of claims 2-5, 10, and 11. Withdrawal of this rejection of claims 2-5, 10, and 11 under 35 U.S.C. §102(a) is respectfully requested.

Summary

It is respectfully submitted that the pending claims 2-5, 7-11 and 17-39 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

CERTIFICATE UNDER 37 C.F.R. 1.10:

The undersigned hereby certifies that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated below and is addressed to the Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450. "Express Mail" mailing label number: EV201891587 US

Date of Deposit: 3-22-05

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March 22, 2005

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